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comprising a peptide of SEQ ID NO: 6 or a fragment thereof, classified in class 514, subclass 2.

Group III includes claims 6, 12, 15, 16, 18 and 20, drawn to a therapeutic composition comprising a peptide of SEQ ID NO: 7 or a fragment thereof, classified in class 514, subclass 2.

Group IV includes claims 6, 12, 15, 16, 18 and 20, drawn to a therapeutic composition comprising a peptide of SEQ ID NO: 8 or a fragment thereof, classified in class 514, subclass 2.

Group V include claim 7, drawn to a peptide obtained by splicing oligonucleotides of a bacteriophage library, screening the library and sequencing the gene, classified in class 530, subclass 300.

Group VI includes claims 14 and 22, drawn to a method for conferring protective immunity by administering a peptide of SEQ ID NO: 5 or a fragment thereof, classified in class 424, subclass 244.1.

Group VII includes claims 14 and 22, drawn to a method for conferring protective immunity by administering a peptide of SEQ ID NO: 6 or a fragment thereof, classified in class 424, subclass 244.1.

Group VIII includes claims 14 and 22, drawn to a method for conferring protective immunity by administering a peptide of SEQ ID NO: 7 or a fragment thereof, classified in class 424, subclass 244.1.

Group IX includes claims 14 and 22, drawn to a method for conferring protective immunity by administering a peptide of SEQ ID NO: 8 or a fragment thereof, classified in class 424, subclass 244.1.

The examiner asserts that Inventions I-IX lack unity of invention due to the absence of a

special technical feature. The examiner further asserts the following:

> The special technical feature unifying the various inventions in the instant application is any one of the four structurally and functionally/immunogenically distinct peptides or a fragment thereof as recited, for example, in claim 6. However, such a peptide or fragment thereof has already been taught in the prior art. For instance, Pichersky (U.S. 5,849,526) taught such a fragment of the peptide sequence, SEQ ID NO: 5, which is long enough to be antigenic. See the attached sequence search report. Therefore, the special technical feature does not define over the prior art. Since the special technical feature is not a unifying feature, the unity of invention is considered as lacking. It is further noted that technically, the absence of a special technical feature would permit the separation of method of using the product from the product itself.

Applicants provisionally elect Group II, claims 6, 12, 15, 16, 18 and 20, with traverse. Claims 1-5 and 8-11 are considered linking claims by the examiner and should be joined with Group II.

37 C.F.R. 1.475 governs Unity of Invention. If a group of inventions is claimed in a single application, there must be a technical relationship between inventions involving one or more of the same or corresponding special technical features. "Special technical features" shall mean those technical features which define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

An application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the listed combinations (1)-(5). The claims of the present invention are directed to a composition comprising a peptide or the peptide or a method of using the composition/peptide. Arguably, the claims of the current case fall into 37 C.F.R. 1.475(b)(3)—a product, a process specially adapted for the manufacture of

said product (though claim 7 is actually the product itself made by the process), and use of said product. **For this reason, the claims should be considered to have unity of invention.**

As for a special technical feature which unifies the claims, the examiner has defined this too narrowly. **The special technical feature is a peptide that immunospecifically binds to a monoclonal antibody obtained in response to immunizing an animal with *Streptococcus pneumoniae* PsaA.**

The examiner first states there is no special technical feature and then states that there is a special technical feature but defines it by the specific species listed, for example, in claim 6, rather than the feature pointed out above by Applicants. The special technical feature in this case cannot be defined so narrowly as to be "any one of the four ...peptides or a fragment thereof."

The examiner further provides no basis for the statement that the special feature is any one of the four species of peptides which are "structurally and functionally/immunogenically distinct." The examiner has not explained why they are allegedly distinct. To the contrary, the listed species of peptides and their fragments have the common functionality of immunospecifically binding to a monoclonal antibody obtained in response to immunizing an animal with *Streptococcus pneumoniae* PsaA.

Still further, the examiner states that such a peptide or fragment thereof has already been taught in the prior art. Specifically the examiner asserts that Pichersky (U.S. 5,849,526) teaches a fragment of the peptide sequence, SEQ ID NO: 5 which is long enough to be antigenic, and thus, the sequence does not define over the prior art.

The examiner has used the wrong comparison for several reasons. First of all, what defines the invention over the prior art is not a peptide of or fragment of SEQ ID NO: 5 or even an immunogenic (or antigenic) peptide of or fragment of SEQ ID NO: 5. However, the examiner has not demonstrated that this sequence is not novel, only that a HUGE sequence of 870 amino acids contains within it 6 amino acids which correspond with 6 amino acids of SEQ ID NO: 5 (which contains 15 amino acids). It would be very easy to find such a short sequence contained within the universe of disclosed sequences. Though these 6 amino acids could be a "fragment" of SEQ ID NO: 5, a "fragment of SEQ ID NO: 5" is not the technical feature of the invention which brings unity nor does Pichersky U.S. 5,849,526 disclose these 6 amino acids but instead discloses a sequence of 870 amino acids (which could be cut into 864 different sequences of 6 amino acids). The proper comparison to the prior art for the peptide species of claim 6 is a peptide described in claim 1 (i.e., a peptide that immunospecifically binds to a monoclonal antibody obtained in response to immunizing an animal with *Streptococcus pneumoniae* PsaA) which is immunogenic against *S. pneumoniae* comprising residues whose sequence is chosen from the group consisting of SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, a fragment of SEQ ID NO:5, a fragment of SEQ ID NO:6, a fragment of SEQ ID NO:7, and a fragment of SEQ ID NO:8. The same is true of claims 12, 15, 16, 18, and 20 as well.

Second of all, though the examiner asserts that the 6 amino acid sequence is "long enough to be antigenic," there is no assertion that this sequence is indeed antigenic, let alone that this 6 amino acid sequence is "a peptide that immunospecifically binds to a monoclonal antibody obtained in response to immunizing an animal with *Streptococcus pneumoniae* PsaA which is

immunogenic against *S. pneumoniae*." Therefore, this 6 amino acid sequence does not anticipate any species actually claimed within claim 6. The claim must be looked at as a whole not just one little piece of the claim. **The examiner has not found art which negates novelty of any of the species within the claims or within the special technical feature.**

Applicants submit that the subject matter of Groups I – IX relate to a single inventive concept. The claims include a composition/peptide and a method(s) of using the composition/peptide which contain the special technical feature of **a peptide that immunospecifically binds to a monoclonal antibody obtained in response to immunizing an animal with *Streptococcus pneumoniae* PsaA**.

There is no basis asserted for why the examiner believes that this shared technical feature is not novel. Thus, the claims meet the requirements of PCT Rules 13.1 and 13.2.

Alternatively, Examiner has improperly attempted to restrict the genus claims into multiple species claims with the restriction requirement. If this is intended to be a species restriction, as discussed in the 37 C.F.R. § 1.141(a), an application may claim a reasonable number of species within a claimed genus as long as at least one genus claim encompassing all of the species is patentable. Applicants assert that this is not an appropriate application of the 37 C.F.R. § 1.141, which is aimed at situations where there are unreasonable numbers of species claimed. Applicants are not required in the present application to elect a species when Applicants have not claimed an unreasonable number of species. Thus, when a genus claim is found to be patentable, Applicants understand that the remaining members of the reasonable number of species must be examined.

Furthermore, Applicants note that in the present restriction the examiner is defining the present peptides by amino acid sequence, rather than by the broader characteristics as claimed in the application. At the very least, the Office's "10 Sequence Rule" should apply in the present restriction. With regard to that "rule," MPEP 803.04 states that the Office will normally search up to 10 unrelated sequences in a single application. The MPEP mentions exceptions to this "10 sequence" rule, but none of them apply to the present circumstances. Thus, even if the Office does not accept the validity of the Applicants' above arguments, Applicants respectfully submit that the Office's own internal procedures call for examination of at least 10 sequences recited in the claims as filed.

Furthermore, a restriction requirement must establish both that (1) the "inventions" are either independent or distinct, and (2) that examination of more than one of the "inventions" would constitute a burden to the Examiner. Applicants note that the restriction/election requirement does not provide sufficient basis to indicate that examination of more than one of the "inventions" would overly burden the Examiner. At most, the examiner represents the alleged distinct inventions are in 1 class/subclass combination for groups I-IV, one for group V, and one class/subclass combination for groups VI-IX. This can hardly be considered a burden. Also, if the examiner is going to search one class/subclass anyway, for example, for a given sequence/fragment, the search would also turn up relevant patents for all of the groups in the same class/subclass (e.g., groups I-IV are all in the same class/subclass search). As such, a search by the examiner relating to a peptide that immunospecifically binds to a monoclonal antibody obtained in response to immunizing an animal with *Streptococcus pneumoniae* PsaA

would necessarily be a search for each of the listed SEQ ID in the dependent claims. Accordingly, the second requirement for a proper restriction has not been met. Applicants thus respectfully request reconsideration of the election requirement.

For the above reasons, reconsideration or withdrawal of the restriction requirement is requested.

No fees are believed to be due, however, the Commissioner is hereby authorized to charge any fees that may be required or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

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Michael Laird — 6/12/03 Date